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# HAI AP News

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HAI AP Est. 1981

Health Action International Asia-Pacific (HAIAP) is part of an independent global network, working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy. HAIAP is an informal network of non-governmental organisations and individuals in the Asia-Pacific Region committed to strive for health for all now. HAI AP News is the organ of Health Action International – Asia Pacific and presents the happenings in the regional campaigns for more rational and fairer health policies and carries material in support of participants' work.

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## ***Message from the Coordinator***

We started the year with a meeting convened by our partner, Drug System Development and Monitoring (DSDM) Program, led by Prof Niyada Kiatying-Angsulee, celebrating 10 years of Compulsory Licensing in Thailand. The meeting allowed some of us the opportunity to meet as HAIAP – Mira, Evelyne, Niyada

and Shila – to discuss HAIAP matters including a project supported by DSDM on drug pricing for the region.

As the first quarter of the year progressed, we discussed plans to possibly convene a HAIAP meeting later in the year. Dr Zafrullah Chowdhury of Gonoshasthya Kendra, kindly offered support in the form of a venue at Savar, Bangladesh and coverage of local transportation, food and accommodation costs. The idea of a HAIAP meeting has now evolved to a wider health and development agenda to Revive Health For All, a vision encapsulated by the late and former DG of WHO, Dr Halfdan Mahler. The meeting is set for 10 – 14 November 2017. It will be managed by an International Steering Committee (ISC) comprising representatives from HAIAP, PHM, MI and MSF. The ISC will first meet from 15 – 16 May 2017 in Savar to confirm the agenda and processes and assign shared tasks for the November meeting.

Also upcoming is the World Health Assembly from 22 – 28 May 2017 in Geneva, Switzerland. Amongst various important agenda items, HAIAP will also watch and hear progress on the Global Action Plan on Antimicrobial Resistance as well as the election of the next DG. The three candidates are from Pakistan, Ethiopia and the United Kingdom. It will be an interesting WHA.

Cheers!

Shila

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## Revive Health for All!

**Meet in Savar, Bangladesh, 10-14 Nov, 2017**

**The initiative:** HAIAP and PHM founding member Dr Zafrullah Chowdhury has formulated the idea of an international meeting to develop strategies for achieving the goal of Affordable Health for All.

Dr Zafrullah noted that since the 1985 [Nairobi Conference on the Rational Use of Drugs](#), for every two steps we have advanced we have gone one step backward. A progressive agenda for people-centred, rational and affordable health care continues to be undermined by powerful vested interests.

He suggests that it is time for us to gather again globally to confront the forces and ideology that oppose *Health for All*.

The date has been set - November 10 -14, 2017.

Activists from all continents will meet together in Savar Bangladesh – hosted by Gonshasthaya Kendra (GK).

An International Steering Committee (ISC) including representatives of the Peoples' Health Movement (PHM) and HAIAP across all continents will meet at GK in Savar, Bangladesh on May 15-16 to develop the program for this significant meeting.

Participants will fund their own travel but GK will provide accommodation and local support. We are extremely grateful to Dr Zafrullah and GK for their generosity and we look forward to the outcomes of the ISC meeting and the opportunity to participate in this important gathering in November.

### HAIAP Satellite

On the sidelines, a satellite meeting of the HAIAP network is also planned with the aim of developing strategies for future communication and work modes as well as realistic activities. HAIAP has not had the opportunity to meet collectively in the last seven years due to funding constraints.

This meeting will be a great occasion to renew ties, exchange and share expectations and plan strategies to attract new and younger health activists.

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## Thailand

### 10<sup>th</sup> Anniversary Celebration of Compulsory Licensing

To mark the 10<sup>th</sup> Anniversary of Compulsory Licensing (CL) in Thailand, the Drug System Development and Monitoring Program, Chulalongkorn University, Bangkok, Thailand, convened a meeting of Health Ministry officials, public health officials, academics, student health activists and civil society representatives on 17th January 2017. Held at the campus of Chulalongkorn

University, the meeting's aim was to review the multiple challenges that the country faces in implementing CL and to conscientise students in the process.

In his opening address, Dr Mongkol Na Songkhla, the former Minister of Public Health, and prime mover of the CL initiative, described the circumstances prevailing in the country during the period leading up to and after the adoption of CL in Thailand. He acknowledged the tremendous support from his Deputy Prime Minister as well as the role of Dr Siriwat, in laying the legal groundwork for CL. He described the attacks on his Ministry by the Minister of Foreign Affairs and Commerce who was more interested in 'protecting international cooperation' than national public health interests. He told stories of incidents during Cabinet meetings where it was observed that some ministers who opposed CL, were in fact stooges of the pharmaceutical industry.

The CL review continued with the sharing of personal views and experiences by Dr Siriwat Thiptaradol, the Secretary General of the Thai Food and Drug Administration. He led the meeting through the history of CL in Thailand, highlighting its impact on public health and lowering the prices of expensive drugs. He shared reminiscences of how pharmaceutical companies tried to derail the CL process in Thailand through: the use of 'experts' from children's and cancer hospitals to support their case; distorting information; and focussing on marketing expensive drugs at private hospitals thereby making medicine price control in Thailand ineffective.

Following the two keynote addresses, there was a symposium on the Process and Impact of CL Implementation in Thailand.

Moderated by Ms Kannikar Kittivejakul participants heard from:

- Achara Eksangri on Procurement, Quality Assurance of Imported Products for CL
- Netnaphis Suchonvanit on Impact on Access to Medicines
- Dr Inthira Yamabhai on The Use of CL: Current Situation and its Economic Impact
- Ms Kajal Bhardwaj and Ms Lottie Rutter gave an excellent overview of international experiences of CL.

The meeting ended with a Panel Discussion between Dr Paiyasakol, Dr Suwit Wibulpolprasert, Dr Nopporn Chenklin and Chlermsak Kittittrakul who informed participants of:

- i. Thailand's 20 Year Plan including its vision for the future based on four pillars (referred to as Thailand 4.0) and the vision and mission of the country's Ministry of Public Health

- ii. the global challenges to access to affordable medicines
- iii. the need to focus on a robust generics industry in developing countries and
- iv. domestic medicines production so that Thailand becomes self-reliant.

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## The TPP is dead..... but

In March 2017 Trade Ministers from some of the TPP countries plus China, Korea and Colombia met in Chile to discuss the future of international trade agreements post-TPP. Unfortunately some governments - including Australia - are pushing to revive the dead TPP.

Protesters are urging governments not to make the same mistakes they did in the TPP and instead to focus on fair trade - especially in the Regional Comprehensive Economic Partnership (RCEP), where damaging TPP-like proposals are still being pushed. With little media attention and the negotiations shrouded in secrecy, there is very low community awareness of the possible dangers of the RCEP.

On March 4, 2017, as RCEP negotiations continued in Japan, MSF sent a letter to all negotiating countries to express serious concern over provisions that threaten to restrict access to medicines for millions of people by delaying access to cheaper medicines and by allowing pharmaceutical companies to sue governments in international tribunals.

MSF writes that proposed provisions in the leaked draft investment chapter could undermine access to medicines by allowing pharmaceutical companies to claim millions of dollars in compensation from governments if they regulate access to medicines. Pharmaceutical companies have sued or threaten to sue governments in Canada, Colombia and the Ukraine because they have tried to make medicines more affordable.

[https://www.msfacecess.org/sites/default/files/MSF\\_assets/Access/Docs/Access\\_letter\\_RCEPinvestmentLetterForNegotiators\\_ENG\\_2017.pdf](https://www.msfacecess.org/sites/default/files/MSF_assets/Access/Docs/Access_letter_RCEPinvestmentLetterForNegotiators_ENG_2017.pdf)

Draft text:

<https://rceplegal.files.wordpress.com/2016/08/03-rcep-wgi10-draftconsolidated-investmenttext.pdf>

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## 2016 PRESCRIRE DRUG AWARDS

Rev Prescire February 2017 Volume 37 N° 400



Three annual *Prescire* Awards, for Drugs, Packaging and Information, are granted in total independence by the *Prescire* Editorial Staff. These awards complement the annual review published at the beginning of each year in the French edition and later in

*Prescire International*. The rules governing the three *Prescire* Awards are available online at

<http://english.prescire.org/en/81/168/52866/0/NewsDetails.aspx>

The 'Pilule d'Or' (Golden Pill) was not awarded for 2016. Awards were announced in February, 2017. Although two drugs were considered 'noteworthy' no new products that were examined were considered to have delivered sufficient therapeutic advantage to be awarded the 'Pilule d'Or' or even a place on the honours list. The two drugs – nivolumab and trametinib - are cancer drugs that were shown to prolong survival by a few months on average but with many serious adverse effects including some that can be fatal.

*Prescire* noted that once again there were few therapeutic advances for the year. There were no packaging awards either. In fact 'yellow cards' and 'red cards' were awarded for packaging deficiencies.

*Prescire* also gives awards for information.

### Quality of information from pharmaceutical companies

A 4-point scale rates the quality of the information provided by companies in response to systematic requests

1. Company provided detailed information including unpublished data and packaging items.
2. Company provided information limited to published regulatory data or packaging information.
3. Company provided minimal information, mainly regulatory and packaging information.
4. Company provided no information.

### Lack of transparency persists

*Prescire* says that pharmaceutical companies provide a lot of information, some new and some already obtained elsewhere. But they are less cooperative when asked to provide relevant, detailed documentation, including unpublished data, which may for example contain details about adverse effects. Some companies choose to be transparent with *Prescire* and demonstrate this by sending quality information. These companies are placed on the Honours List. And those rated as 'Outstanding' provided useful, detailed data without delay and sometimes without being asked. Other drug companies fail to respond to some or all requests for information, or provide only limited data. Some of them delay their response, then fail to provide usable information. Some omit the most important or sensitive data. Red Cards are given to highlight persistent deficiencies in the provision of information by certain drug companies.

As in previous years, few pharmaceutical companies embraced transparency in 2016 by agreeing to share all

the data they hold with healthcare professionals. Yet transparency demonstrates a company's commitment to improving medication safety. See all details here:

<http://english.prescrire.org/en/81/168/52866/0/NewsDetails.aspx>



## No thank you !

*Prescrire* has also published a 'No Thankyou' Guide to help prescribers decline invitations from pharmaceutical company representatives.

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Some little snacks or a buffet at a discussion on community hospital relations, a departmental meeting, training session or a care home or pharmacy team meeting? Yes, why not, refreshments can be convenient, convivial and very welcome in the middle of a busy working day. But no thank you, not when a pharmaceutical company is footing the bill, in the interests of 'staying in touch with healthcare professionals'.

That is how we are insidiously influenced, instead of gathering impartial information on drug treatments. And, in France, accepting this type of freebie would be enough for us to see our names listed as 'recipients of benefits from a pharmaceutical company' on the Ministry of Social Affairs and Health website, that aims at preserving the necessary relationship of trust between citizens, users and the multiple actors in the health system.

<https://www.transparence.sante.gouv.fr/>

Actually, it is easy enough to eat and drink at our own expense and to have the courage simply to say 'no thank you' to pharmaceutical companies and their representatives.

It can be difficult to make a habit of saying no, but doing so will be a source of great satisfaction. Being able to say 'no thank you' to firms seeking to influence healthcare professionals is crucial to obtaining information and training that prioritises patients' best interests. It is also crucial when choosing a drug, especially when it does more harm than good and exposes patients to disproportionate risks. However, dozens of such drugs are on the market because pharmaceutical companies have been granted marketing authorisations and are allowed to keep promoting them.

As a rule, it takes many years before they are withdrawn. Years during which we are authorised to prescribe or recommend these drugs, as well as being permitted to accept little gifts from the pharmaceutical companies.

But to do so is not beneficial to patients. Even when a patient believes they can trust a particular drug: it simply reinforces their misplaced trust. And it would put us in a bad position as a de facto accomplice in the event of an unfortunate outcome for a patient who is adversely affected by the drug.

It is better to pledge to saying 'No thank you, we will not begin treatment with this dangerous drug, there are better options'. Pledge also to saying, backed by robust evidence, 'No thank you, we are going to discontinue this treatment as it is too dangerous, before serious problems arise.

Knowing how to say 'No thank you' is crucial if healthcare professionals are to do their job well.

*Translated from Rev Prescrire February 2017*

<http://english.prescrire.org/en/SummaryDetail.aspx?Issueid=181>

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## Antimicrobial Resistance

### *Thailand: Colistin use in animals*

#### Introduction

Colistin is a 'last-resort' broad-spectrum antibacterial agent, that is used to treat multi-resistant *Acinetobacter baumannii* and certain other *spp.* Some Gram negative rods are intrinsically resistant to colistin: *Burkholderia cepacia*, *Serratia marescens*, *Moraxella catarrhalis*, *Proteus spp*, *Providencia spp* and *Morganella morganii*.

Therefore, colistin use and misuse raises the potential for the development of significant bacterial resistance with profound clinical impact on healthcare systems.

It should be an infrequently used antibiotic reserved for specific organisms only. Prescription of this antibiotic must be strictly controlled by specific treatment protocols.

#### ***FDA to limit use of colistin to curb drug resistance***

*Adapted from the Nation report - February 01, 2017 01:00*

Thai FOOD and Drug Administration (FDA) officials have announced controls on the drug colistin after reports that farmers in Nakhon Pathom and Suphan Buri have been feeding it to pigs.

The FDA in February, banned the oral intake of the drug for people and will only allow it to be given to animals if prescribed by a veterinarian.

Colistin, described as an 'antibiotic of last resort' has been sold over-the-counter at pharmacies, but public sale of the drug was curbed because of the risk of people getting infected with serious drug-resistant bacteria.





Reports that pigs were getting food laced with colistin has worried the public and doctors fear such ‘frivolous’ use could lead to the spread of deadly bacteria that are resistant to antibiotics. Bacteria that can resist ‘last resort’ drugs such as colistin are unlikely to be cured by other medicines used in early phases of treatment, officials have said and life threatening bacteria can become resistant to this life-saving antibiotic.

Thai FDA deputy chief Prapon Antrakul said his agency and the Livestock Development Department had agreed to make colistin a controlled medicine for use only under the supervision of a veterinarian – as per the fourth article of a strategy approved by the Cabinet to counter drug resistance and control the use of antibiotics in animals.

Use of colistin for humans would also be restricted to injections to prevent frivolous use, he said. Both changes were tabled at the FDA board’s meeting in February.

‘The residue of colistin in pork meat is only a small amount, so it would not directly harm consumers. But we’re worried that colistin in pig feed could lead to drug-resistant bacteria,’ Prapon said. He urged people to properly cook pork meat so bacteria are killed and drug-resistant bacteria are eliminated.

HAIAP’s Governing Council member and Thai Drug Watch Group Manager, Dr Niyada Kiatying-Angsulee said uncontrolled use of colistin could lead to bacteria with a drug-resistant gene that could lead to many human deaths in the future.



Dr Niyada cited a report that 96 used bottles of antibiotics were found at a farm with 300 pigs at Nakhon Pathom. She said the bottles had contained nine strong antibiotics including seven bottles of ceftriaxone, a

bacterial antibiotic only given via injection to hospitalised patients; and unregistered colistin.

She said a study of a pig farm in China in 2015 had shown horizontal gene transfer of bacteria from animals to humans and vice versa. This led to the important discovery of a gene with mobilised colistin resistance (MCR-1).

Dr Niyada said media in the United States reported the first MCR-1 gene in *E coli* bacteria in May 2016, which was found in a Pennsylvania woman. The new discovery caused global alarm about colistin ‘abuse’. Dr Pisonthi Chongtrakul from Chulalongkorn University’s Faculty of Medicine said the American case was alarming because *E coli* should be cured immediately by colistin so the case was unprecedented.

Pisonthi said feeding colistin to pigs without supervision by a veterinarian could lead to two dangers. First, if farmers slaughtered pigs for sale in less than the three days needed for the body to naturally get rid of the drug residue, consumers could end up accumulating it and their kidneys would be affected.

Secondly, colistin was used to treat drug-resistant germs like *Acinetobacter baumannii* bacteria found on medical equipment; so use of the antibiotic could cause a serious drug-resistant gene to be passed from incoming bacteria to other bacteria in people’s bodies, he said.

Livestock Department chief Apai Suttisunk said the agency had controlled and monitored use of the drug while encouraging farms to operate according to international standards. Over 10,000 livestock farms have been certified for producing meat that was free of antibiotics or contamination, along with 2,700 shops that sell meat.

He said the department would punish farms that use illegal drugs or over-used medicine, adding it would also seek to control importers of livestock drugs and force manufacturers to abide by the law.

The success of agencies in boosting bio-safety at farms had led to a gradual decrease in antibiotic abuse, Apai said. He added that the department would join relevant agencies to implement guidelines to control the use of veterinary medicines in livestock production, and abide by the national strategy to manage antibiotic-resistance from 2017 to 2021, which includes appropriate control of the use of antibiotics administered to animals.

<http://www.nationmultimedia.com/news/national/30305408>

See also: Increases of Antibiotic Resistance in Excessive Use of Antibiotics in Smallholder Dairy Farms in Northern Thailand  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4092948/>

[W. Suriyasathaporn](#),<sup>1,\*</sup> [V. Chupia](#),<sup>2</sup> [T. Sing-Lah](#),<sup>1</sup> [K. Wongsawan](#),<sup>2</sup> [R. Mektrirat](#),<sup>2</sup> and [W. Chairi](#)<sup>1</sup>

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## India gears up to tackle AMR

<http://www.epnetwork.org>

In the third week of February 2017 the Indian Ministry of Health announced special audits of prescriptions of antibiotics made by hospitals and pharmacies around the country.

The move was part of India's multi-pronged strategy against anti-microbial resistance (AMR), that threatens the effective prevention and treatment of an ever-increasing range of infectious diseases.

Under the new initiative dispensers of antibiotics will have to upload all the prescriptions issued and received by them for evaluation by a central agency. According to senior Ministry of Health officials this will help the government gather much needed data on AMR, that in turn will help implement the country's new National Action Plan, developed jointly with the World Health Organization (WHO). See the plan here: <https://tinyurl.com/l34awqy> and see the Delhi Declaration on AMR here: <https://tinyurl.com/mhhbhlm>

In early 2016, India's state-run National Centre for Disease Control released standardized treatment guidelines for practitioners across the country to rationally use currently available antimicrobial agents. India is also in the process of building a surveillance network to monitor resistance around the country.

Drug control authorities have also restricted sales of 46 antibiotics and anti-tuberculosis drugs in recent years apart from carrying out a campaign for raising public awareness on the need to protect the efficacy of these medicines. The full report can be read here:

<https://tinyurl.com/mbq2ose>

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## More News from India

*Information supplied by Dr Mira Shiva*

### Cardiac Stents

Cardiac stent prices were a cause of concern to the Parliamentary petition committee when they were first brought within the National List of Essential Medicine. Only after that, using a Drug Price Control Order on February 13, 2017, the National Pharmaceutical Pricing Authority (NPPA) fixed ceiling prices of Bare Metallic Stents at Rs 7260 (US\$ 112) per unit and the those of Drug-eluting Stents and Biodegradable stents at Rs 29,600 (US\$ 460) per unit. This was a very important action by NPPA to prevent overcharging of cardiac stents and to try to make them more affordable.

Dr Mira said the issue now is about the price of cardiac stents on one hand and charges of hospitals for the

cardiac procedure and charges to patients receiving cardiac stents. The public and patients have been very relieved because a large number of people could not afford treatment of their loved ones.

### The case of the unbanning of the Fixed Drug Combinations (FDCs)

In December 2016 the Delhi High Court quashed the Ban order of the Drug Controller General of India on 344 Fixed Dose Combinations of Drugs (FDCs) that had been taken a few months earlier, on legal procedural grounds. Safety and Efficacy concerns were not considered.

That was considered a huge setback to efforts aimed at bringing a semblance of order into the absolute anarchy that exists in India's pharmaceutical market (see HAIAP News December 2016).

The All India Drug Action Network filed a Special Leave Petition in the Supreme Court of India to be allowed to intervene. The Hearing was held on 31st March and an order was granted to list the case on 22nd July in the Supreme Court.

Special Leave Petitions in India (SLPs) hold a prime place in the Judiciary of India, and are provided as a 'residual power' in the hands of Supreme Court. If a judgement of the court 'shakes the conscience and shocks the sense of justice', the Supreme Court of India at its discretion may grant *Special Leave* to appeal from 'any judgement, decree, determination, ...'

The aim of the SLP in the Supreme Court is to change that ('unbanning') order as it was given on the ground that the procedure was not followed as in the Drugs and Cosmetics Act 7. The Drug Technical Advisory Board should have given its recommendations of banning to the Drug Controller General of India and not to the Kokate Committee. Therefore the Ban order was said to be invalid.

### Generic Medicines

In the meantime the Prime Minister has said that a code will be passed to make Generic Medicine Prescribing mandatory by Doctors. A meeting was held on April 21 in the Department of Pharmaceuticals by the Committee for ensuring enhanced availability of drugs to the poor.

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## Strings attached to patient lobby groups

*Jane McCredie - Sydney-based health and science writer in MJA Insight March 13 2017*

<https://tinyurl.com/mbq2ose>

When a new treatment for Duchenne Muscular Dystrophy (DMD) was put up for approval in the US in 2016, patient advocacy groups and hundreds of individual patients and their families packed the Food and Drug Administration's (FDA) Advisory Committee

meeting to give emotional testimony in favour of the drug.

Committee members found themselves under 'intense and near-incessant pressure from a large public audience', [Nature reported](#).

Despite that pressure, the committee voted narrowly against approval of eteplirsen (Exondys 51), based on a lack of clear evidence of efficacy for the treatment, which costs around US\$300 000 a year per patient.

But, as FDA scientists were soon to find out, it's hard to resist the appeals of children who are suffering and their parents.

In [September 2016, after a sustained campaign from patient advocacy groups, the regulator](#) overruled the scientific committee's findings and announced that the drug had been granted accelerated approval.

A member of the Advisory Committee responded, telling *Nature* the decision lowered the agency's evidentiary standards for drug effectiveness to 'an unprecedented nadir'.

Of course, everybody wants the best for children facing a devastating genetic condition like DMD. But we also need to know that approved treatments are safe and effective and to understand the interests of those lobbying on their behalf.

If patient advocacy groups are going to wield this kind of influence in the regulatory system, they need to be transparent about any connections they may have to the commercial interests they are supporting.

This has been written about before but not much has changed, at least in the US, if a new study is any guide.

Researchers from the University of Pennsylvania examined annual reports and other records of 104 large patient advocacy organisations to assess their connections to industry and how fully these were disclosed. The report card, published in the *New England Journal of Medicine*, isn't good.

At least 83% of patient support organisations received financial support from drug, device or biotechnology companies, but almost none of them fully disclosed the amounts of those donations or how they were used.

Of the 57% that gave some information about donation amounts, almost all gave a range rather than a precise figure. And the ranges could be very wide, extending in some cases from below US\$250 to over US\$1 million.

Inadequate disclosure meant the researchers were unable to estimate the proportion of most organisations' revenue that was provided by the industry, making it impossible to know just how dependent they were on the companies whose interests they could end up promoting.

For what it's worth, for those organisations that did provide enough information to estimate this, the researchers found that about 40% received more than 10% of their revenue from industry donations.

It's not just a question of cold, hard cash. At least 39% of patient organisations had a current or former industry executive on their board, and at least 12% had an industry executive in a board leadership position, such as chair or deputy chair.

Those figures are almost certainly an underestimate, as more than a quarter of organisations did not disclose employment details for board members.

In Australia, Members of Medicines Australia (Industry organisation) are [required to disclose direct financial support for health consumer organisations, though the organisations themselves may well not disclose it](#).

And, as the example of board positions shows, direct cash donations are not the only way industry can influence the direction of an organisation.

Corporate generosity is a good thing, provided there are no strings attached. Full disclosure is the only way to ensure that's the case.

<http://www.doctorportal.com.au/mjainsight/2014/37/jane-mccredie-charitable-deception/>

<http://www.nature.com/nm/journal/v22/n11/full/nm.4234.html>

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## Potential price reductions for cancer medicines on the WHO EML

Melissa J Barber, Dzintars Gotham, Andrew Hill

*Melissa Barber shared with E-drug a study demonstrating that prices of cancer medicines could be significantly reduced. The study was presented as a poster at the ECCO 2017 European Cancer Congress 27-30 January 2017 in Amsterdam, Netherlands.*

The full poster can be seen here <https://tinyurl.com/k52ve4j>

### Abstract

**Background:** The majority of cancer diagnoses occur in low and middle income countries, where there were an estimated 14 million incident cases in 2012, and a projected 22 million cases by 2035. Global spending on oncology reached \$100 billion in 2014. High prices of cancer treatments are a barrier to access in low and middle income countries, where monthly prices often exceed annual incomes.

Over 17 million people with HIV and AIDS are on treatment with low-cost generic anti-retrovirals. We investigated the feasibility of similar price reductions in medicines for cancer. The World Health Organization's Essential Medicines List (WHO, EML) lists 39 cancer medicines that are a high priority for treatment worldwide. The cost of the active pharmaceutical ingredient (API) is a central component of the cost of drug production.



**Methods:** Current unit prices in the UK, Spain, and India were collected for cancer drugs in the WHO EML using public databases. Data on per-kilogram cost of exported Active Pharmaceutical Ingredients (API) were retrieved from an online database of Indian export logs, and used in an established costing algorithm to derive estimates for generic prices ('target prices') assuming robust competition: per-dose API costs were calculated, to which excipient costs of US\$2.63 per kg of finished pharmaceutical product and per-tablet costs of production of US\$0.01 were added, plus a 10% profit margin accounting for a 26.6% average tax on profits (assuming manufacture in India.)

**Results:** Calculated target prices for tablets were median 1% above prices in India, 85% below current prices in the UK, 89% below prices in Spain, and 86% below prices in US (Veterans Affairs pricing) (see Table 1 on the poster). For injectable formulations, the lowest current price found for finished pharmaceutical products in India were median 12% above the estimated cost of API, and 94% above final product current prices in Spain, 98% above prices in the UK, and 87% above prices in the US (Veterans Affairs pricing) (see Table 2 on the poster).

**Conclusion:** Mass production of cancer drugs on the World Health Organization Essential Medicines List could significantly lower prices.

Significant reductions in cancer drug prices could allow substantial expansion of cancer treatment coverage, across a wide range of countries.

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## MSF Fair Shot campaign

### – **to lower the price of pneumonia vaccine**

Thanks to Michelle French Senior Manager, Communications  
MSF Access Campaign [www.msfacecess.org](http://www.msfacecess.org)

April 20th, 2017, Medecins Sans Frontieres (MSF) launched a new online tool called 'Your Stock, Your Voice'. It is part of A Fair Shot campaign, through which MSF has been campaigning to ask Pfizer and GSK to lower the price of the pneumonia vaccine to \$5 per child (for all three doses) for all developing countries.

Most people don't know offhand if they actually have investments in Pfizer and GSK through their retirement plans (i.e. 401k's) or mutual funds. 'Your Stock Your Voice' makes it easy for users to verify if they have

investments in the companies and prompts them to take action. The key here is to not ask people to divest, but to actually leverage their investor status to hold the companies accountable.

Check it out here: <http://afairshot.org>

You can read *Newsweek's* coverage here:

<https://tinyurl.com/kvv82ap>

MSF hopes Pfizer and GSK will be persuaded to reduce the price of the vaccine to \$5 per child for all three doses in all developing countries. Concrete information about current prices is hard to obtain. The prices for the two vaccines vary around the world. Sarah Spencer, a spokeswoman for GSK says GSK does not publish the prices for individual vaccines in each country because of anti-competition rules and 'commercial sensitivities.'

Vaccines against pneumonia have been available since 2000 and the Centres for Disease Control and Prevention and the WHO recommend the immunization for all children younger than two years old, particularly in those countries where high numbers of children are dying from the infection. MSF now wants Pfizer and GSK to lower the vaccine price to \$5 for three doses for all low- and middle-income countries, regardless of any specific crisis. The companies have so far declined, which is where 401,000 holders and other investors can enter the picture.

'Can minor shareholders have any sway over pharmaceutical pricing practices? Probably not', says Mike Scherer, a former economics professor at the Harvard Kennedy School. He points out that the complaint of one shareholder, or even many shareholders, is unlikely to be heeded when a company has thousands of investors. Scherer says. 'Bad publicity is much more likely to goad companies into lowering prices than are complaints from a scant group of shareholders'.

Nevertheless, MSF believes that, if enough individuals take action, Pfizer and GSK could relent. Scherer cites the history of HIV drugs' prices - activism was crucial in forcing drug makers to lower the prices for those medications in low-income countries. Spencer insists that, as a publicly traded company, GSK welcomes feedback from shareholders 'on issues that matter to them.' And MSF has accomplished such goals - as evidenced by the drastically reduced price of the pneumonia vaccine during emergencies.

Michelle French, On behalf of the A FAIR SHOT team,



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## Feature: Pacific Regional Consultation February 14 – 17, 2017

Compiled by Beverley Snell and colleagues

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In February 2017, representatives from the pharmaceutical sectors of 13 Pacific Island Countries (PICs) met in Nadi, Fiji, to share experiences and learn from each other. The consultation was sponsored by the Western Pacific Regional Office of WHO. Three major themes were Quality Assurance of pharmaceutical products, Antimicrobial Stewardship, the status of traditional medicines in the region and vaccine management.

- To support countries to strengthen risk-based post-market surveillance on quality of medical products

### Traditional medicines:

Pacific Island traditional medicines are mainly plant derivatives used for their carminative properties. However imported Chinese and Indian products that do not satisfy regulatory requirements are potentially dangerous. So recommendations were:



The summarised recommendations were

### Overview - For WHO:

- Promote communication and information exchange between Pacific Island Countries
- Organize regular sub-regional meetings for the PICs in every 2-3 years
- Publish and regularly update country profiles for PICs

### Quality assurance of medicines

#### For Member States:

- To contribute to regular exchange of information on medicines policies and quality assurance of medical products
- To strengthen pharmaceutical regulation by implementing licensing schemes for pharmaceutical establishments including importers, wholesalers, and distributors

#### For WHO:

- To facilitate information exchange on quality of medical products through the new regional quality assurance platform

#### For Member States:

- To regulate imported Traditional & Chinese Medicines finished products and practitioners trained in other countries
- To assess potential risks and benefits of indigenous traditional medicine in the health care system

#### For WHO:

- To share information on regulation standards for products and practitioners in Member States in the region
- To provide technical support for conducting situation analysis and developing policy/regulatory system

### Antimicrobial resistance

#### For Member States:

- To develop and implement country specific national action plans on antimicrobial resistance
- To undertake regular awareness raising and advocacy on antimicrobial resistance and rational use, including celebration of annual world antibiotic awareness week.

**For WHO:**

- To provide technical support for finalization of national action plans on AMR and monitoring implementation and support world antibiotic awareness week campaigns in Pacific Island Countries..
- To support capacity building for generation of quality data on AMR and antimicrobial consumption in Pacific Island Countries.



World Health Organization  
Western Pacific Region

**MEETING ON QUALITY ASSURANCE AND RATIONAL USE OF ESSENTIAL MEDICINES IN THE PACIFIC ISLAND COUNTRIES**  
14 -17 FEBRUARY 2017  
NADI, FIJI

**Vaccines**

**For Member States:**

- To implement a cold chain monitoring system for vaccines and other biologicals
- To build capacity on pharmacovigilance and causality assessment involving all stakeholders

**For WHO:**

- To provide technical assistance on cold chain and waste management
- To provide technical assistance in building capacity, establishing governance structure and information

sharing, and raising awareness to consumers and Health Care Workers on pharmaco-vigilance

**Sharing Quality Assurance Information**

A highlight of the meeting was information about the development by Michael Nunan and colleagues of a regional website for sharing quality assurance information about suppliers and products. Quality Assurance is an onerous task for busy pharmacy leaders who are responsible for overseeing all facets of the systems, particularly when new companies are tendering their products. This resource was received with considerable excitement.

Documentation for suppliers includes

- Product inspection reports (Visual inspection, lab testing)
- Results and documents provided by participating countries, including Recalls.

A flag system is used for quick checking of products and their manufacturers: Flags attach to items, manufacturers and suppliers

**Green:** Item passed laboratory testing

**Blue:** Item passed visual inspection but has not been lab tested

**Orange:** Item failed visual inspection but has not been lab tested

**Red:** Item failed lab testing.

Data will soon be shared automatically to stock management software (e.g. *mSupply* etc). Participating countries can log in to view and add information.

Participants were extremely grateful to WHO for bringing them together for this valuable meeting. They had not met together for some years due to the decreased WHO funds available.

**New International Medical Products Price Guide Available**



This **Guide** was formerly known as the International Drug Price Indicator Guide. It has been renamed to better reflect the contents, since it includes more than 80 non-pharmaceutical products. It still provides a spectrum of prices from pharmaceutical suppliers, international development organizations, and government agencies.

The Guide assists supply officers to determine the probable cost of medical products for their programs, allows users to compare current prices paid to prices available on the international market or assess the potential financial impact of changes to a medicines list,

and helps to support rational medicine use education. The latest edition of the Guide includes more than 35 new items, with prices from 27 sources. This edition of the \*Guide\* has prices for more than 1,100 products.

In addition to a new name and new data, there is a new website for the Guide. Please visit the new web version at [www.mshpriceguide.org](http://www.mshpriceguide.org)

You can search from this site as well as download .pdf files of the print version and spreadsheets with the median prices from each year. The site allows you to define and save lists of products that interest you, so that you can compare your prices, estimate costs, or download data. The new site graphs the historical prices for each product so that you can easily see changes over time.

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## Feature: Reflections on World Health Day 2017

*Martin Khor: Executive Director of the South Centre*

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*Martin Khor is the Executive Director of the South Centre, a think tank for developing countries, based in Geneva.*

*He is the former Director of the [Third World Network](#) which is based in Penang, Malaysia.*

What's the most precious thing in the world which unfortunately we take for granted and only realise its true value when it is impaired? Good health, of course.

That's something many people must have reminded themselves as they celebrated World Health Day on 7 April.

Attaining good health and well-being may be a top priority goal, but achieving it is elusive for almost everyone, and next to impossible for the poor.

In the 1980s, the World Health Organization's Director-General Halfdan Mahler steered through a declaration with the popular slogan 'Health for All by the year 2000'.

We crossed into the 21<sup>st</sup> century without realising that noble goal. Although health has improved in most countries, due mainly to cleaner water and sanitation, but also due to better treatment, much remains to be done.

In recent years, the slogan 'Health for All' has been strengthened by the recognition in the United Nations of health as a human right. It has been further boosted by the adoption of the principle of universal healthcare.

This means that no one should be deprived of health care even if they are too poor to afford it. Unfortunately, while the prices of old medicines whose patents have expired have gone down, there are many newer medicines which are too expensive for the ordinary person to afford.

That's because a company that owns the patent has a monopoly over the production and sale of the medicine. Since there are no competitors, the price can be skyrocketed to high or to even astronomical levels. The patent normally lasts 20 years.

For example, the prices of medicines for HIV and AIDS had been at the level of US\$15,000 per person per year in the United States. For most AIDS patients in Africa and developing countries elsewhere, this meant they could just not afford them.

Since those medicines were not yet patented in India, because India had until 2005 to implement the TRIPs Agreement of the World Trade Organization, an Indian drug company, CIPLA, was able to sell and distribute a three-in-one combination drug for about US\$300 per

person per year. Later, the price levels of the generic producers fell further to about US\$60.

Millions of lives around the world were saved by competitor generic companies which could sell the medicines at more affordable prices. Health agencies like the Global Fund for AIDS, TB and Malaria were set up and took advantage of the falling prices to make AIDS medicines available to poor countries.

In recent years a similar storm has been brewing over the prices of new drugs for Hepatitis C, a life-threatening disease which millions around the world suffer from. One of the drugs is sofosbuvir, which has an efficacy rate of 95% and with fewer side effects, but is being sold in the US for about US\$85,000 per course of treatment.

Some generic companies in India have been allowed by the patent-holding company to produce and sell it at their own price level, which is currently around US\$200-400 per patient for a course of treatment. They sell these drugs in India and in lower income countries at these much cheaper prices.

But they are not allowed by the patent holder to sell in most middle income countries, so almost two billion people in developing countries cannot have the medicine at the affordable price.

### **What can be done?**

While the TRIPs Agreement mandates that patents have to be granted for genuine inventions, countries are also allowed to issue a compulsory licence or a government use licence to import or manufacture generic versions of the patented drug, if the original medicine is found to be too expensive. Thus those countries taking this action can access affordable generic drugs.

The patent owner will receive a remuneration (usually a percentage of sales revenue) from the generic company or the government that is selling the generic product.

Countries can also carefully examine companies' applications for patents and reject those that are not genuine inventions, for example when a new patent is applied for a product with just a different dosage or the use of the same drug for another disease.

In reality, there are many new medicines already in existence or coming on stream that are patented and therefore out of reach of most patients. This tension between monopoly for patent holders (usually the big drug companies) and access to medicines for all has



become acute and there are social movements around the world, both in developing and developed countries, that are fighting for patient's rights and against excessive monopolies by companies.

### **Excessive sugar consumption**

Another interesting recent development is the recognition that too much sugar consumed can lead to and has led to epidemics of many ailments, such as obesity, heart problems, diabetes. The authorities in more and more countries are taking action to limit sugar content - for example of soft drinks. The WHO has guidelines on sugar consumption and on how to avoid excessive sugar in many foods, especially those taken by children.

For world health day, consumers should resolve to cut down on sugar in their drinks and food.

### **Antimicrobial resistance**

An emerging threat that endangers human life is the resistance of bacteria and other pathogens to antibiotics and other antimicrobials.

Many antibiotics are no longer effective for an increasing number of patients with a wide range of ailments,

including TB, pneumonia, malaria, gonorrhoea and skin infections. Diseases that were once easily cured are now developing resistance, meaning the drugs don't work anymore.

We have stark warnings from top public health officers like the WHO Director-General Margaret Chan and the United Kingdom's Chief Medical Officer Dame Sally Davies, that we are approaching a post antibiotic era. In the future, even a simple scratch on a child's knee or infection during surgery could lead to death, according to these officials.

Last September, political leaders meeting at the UN General Assembly pledged to take serious action to deal with antibiotic resistance.

Finally, the World Health Assembly in May this year will be electing a new Director-General for the WHO. There are three candidates from Pakistan, Ethiopia and the United Kingdom. May the successful candidate do a superb job in addressing all the ailments, diseases and problems in world health.

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## **HAI Global Insulin Access studies**

The ACCISS Study has two new reports and a fact sheet to share with the network!

The [Access to Insulin Issues Paper Update](#) provides a summary of the work done in the first year of the study.

The [Biosimilar Insulin Regulatory Profile](#) available at <http://haiweb.org/> outlines the regulatory pathways for biosimilar insulin and the challenges that companies might face in seeking regulatory approval. It also comes with a separate [fact sheet](#), for those looking for a quicker read!

The fact sheet and the issue paper update can be found on the HAIAP website also.

<http://www.haiasiapacific.org/wp-content/uploads/2017/04/AccessstInsulinIssuesHAI2017reduced-2.pdf>

<http://www.haiasiapacific.org/wp-content/uploads/2017/04/Biosimilar-InsulinRegulatoryReportFactsheet2017-1>